Neifeld Docket No: AMOI0010U-US

Application/Patent No: 10/724,852 USPTO CONFIRMATION NO: 2156

File/Issue Date: 12/1/2003

Inventor/title: PIERS, ET AL./Multifocal Opthalmic Lens

Examiner/ArtUnit: IZQUIERDO/3738

37 CFR 1.131 Declaration of Henk Weeber

- 1. I am a named inventor on United States patent application 10/724,852, filed 12/1/2003.
- 2. I understand that the examiner has rejected claims in this application based in part upon WO 02/084381. I understand that WO 02/084381 has a publication date of October 24, 2002.
- 3. My co inventors and I invented, by designing, modeling, prototyping, and testing lenses that correspond to claim 216, before October 24, 2002. The design, modeling, and testing showed that the claimed lenses worked for their intended purpose of providing a near and a far focus, and correcting for spherical aberrations.
- 4. I am told that claim 216 reads as follows:
  - 216. (New) A diffractive multi focal intraocular lens comprising:
  - a first refractive surface;
  - a second refractive surface;
- a diffractive pattern on at least one of said first refractive surface and said second refractive surface;

wherein said first refractive surface, said second refractive surface, and said diffractive pattern result in a base focus and an additional focus; and wherein at least one of said first refractive surface and said second refractive surface has an aspheric component to its shape.

- 5. I believe the report attached to this declaration and identified as attachment 4 shows that the lenses prototyped and tested had features corresponding to the elements defined by claim 216, as indicated by at least the following references to the claims and the report.
- 6. Page 9 section 4 and page 10 Figure 5 specify the prototype lens designs. Page 9 section 4 specifies that the prototype intraocular lens design included a refractive surface contoured to include a diffractive pattern with step height and ring diameter values adapted to silicone HRI material to provide near and far foci, and another lens surface optimized for symmetrical Zernicke terms for near and far vision. Thus, the report shows that the intraocular lens design had the claimed first refractive surface, second refractive surface, diffractive pattern, and

resulted in a base focus and an additional focus. Figure 17 on page 18 shows coefficients of CC, AD, and AE for aspheric terms of an equation defining the anterior surface of the IOL. CC (the conic constant), AD, and AE are referred to on page 7 in section 3.1.6 with respect to an algorithm for determining optimum aspheric components of the surface shape of the IOL. Thus, the report shows that the intraocular lens design had the claimed refractive surface having an aspheric component to its shape.

- 7. Page 10 Figure 4 specifies the theoretical performance of the prototype lens designs. Figure 4 shows that the aspheric designs provide far and near foci wavefront aberration values that are better than for a spherical design.
- 8. Page 13 section 4.3 reports on optical performance testing of actual prototypes based upon the prototype designs. This section of the report states that "all results showed that the lenses were close to the design in the sub-micron range (average deviation from step height 0.04 micrometer)" indicating no problem in fabrication.
- 9. Pages 13 to 17 contain various measurements and comparisons of the prototype aspheric lenses to a spherical bifocal lens. The report states in this respect on page 15 that "the results show that the optimized top and the Z9000 top [sic; prototypes] have comparable performance in terms of MTF. At 5 mm they are much better than model 811E." At page 17 the report states that add power is "very well on target" and that the far power "is a little off and needs fine-tuning." On page 17, section 4.3.5 identifies the desired "fine tuning."
- 10. On page 18, section 5 is entitled "DISCUSSION" and it states that the "report shows that the Tecnis Z9000 design principles can be successfully applied on bifocal lenses" and that the "improvement of the ZM001 [sic; design prototype], compared to model 811E is significant ... for the larger pupils."
- 11. The report attachment 4 was the culmination of work testing a bifocal variation of the Z9000 lens. The design and testing was successful, and it indicated to me that the designed lenses worked for their intended purpose of providing near and far focal points.
- 12. I have been warned that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of the application or any

patent issuing thereon. All of my statements are based upon my own knowledge and are true or are statements made on information and belief and I believe them to be true.

12 april 2007

Henk Weeber

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Wednesday, April 11, 2007

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